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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,336	08/20/2001	Neil James Butt	7174555913	6843

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EDWARDS & ANGELL, LLP  
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BOSTON, MA 02205

EXAMINER
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MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 02/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/856,336

Applicant(s)

BUTT ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 26 January 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☒ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: 27,34,35,43,44 and 47.  
Claim(s) rejected: 1,3-26,28-33,37-42,45 and 46.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☒ Other: See Continuation Sheet.

Continuation of 3. NOTE: The proposed amendment would raise the following new issues that would require new consideration: The instant invention is drawn to a method for isolating plasmid DNA comprising extracting the plasmid in a mixture of butanol, chaotrope and water under denaturing conditions. Claims 24-35 and 41-47 are drawn to an extraction mixture comprising butanol, chaotrope and water. Claims 24, 25, 30 and 31 have been amended to recite that the butanol in the extraction solution forms an organic phase during the extraction process. These amendments change the scope of the claims and as such raises new issues requiring further consideration and a prior art search. The specification does not explicitly teach that butanol forms an organic phase during the extraction process. Rather the specification teaches that the extraction mixture during the extraction process results in an aqueous and organic phase, the plasmid DNA is found in the organic phase and the genomic DNA in the aqueous phase. Therefore, the amendment to the claims raises issues of new matter.

Continuation of 5. Applicant's reply has overcome the following rejection(s): If the claims were to be amended, applicants' reply would have overcome the rejection of claims 1, 3-12, 15-23 and 37-40 under 112, second paragraph for use of the word "substantially". Applicant's arguments would have overcome the rejection of claims 1, 3-7, 9-23, 25, 26, 37-40 and 45-46 for lack of written description regarding the genus of basic conditions and bases to denature the DNA. Finally, applicants amendment would have overcome the art rejections under 102 and 103.

Continuation of 11. does NOT place the application in condition for allowance because: the applicant's arguments are moot in view of the non-entry of the after final amendment.

Continuation of 13. Other: Applicants traverse the rejection under 35 USC 112, first paragraph, for lack of written description on page 17-18 of the amendment filed 1/26/05. Applicants argue that the use of alcohol as a precipitating agent is well known in the art and cite use of isopropanol and ethanol. Applicants argue that the claims do not relate simply to any alcohol but to a subset of alcohols that can precipitate the plasmid DNA from the butanol.

Applicants arguments filed 1/26/05 have been considered but are not persuasive. As applicants have stated, the claims are not drawn to use of any alcohol but to a subset of alcohols that can precipitate the plasmid DNA from the butanol phase. However, applicants claims recite the use of any alcohol. And applicants have only disclosed that ethanol has the correct properties to precipitate the plasmid DNA from the butanol.

Applicants have added new claims 48 and 49 and have included the term "substantially". The term "substantially" is a relative term and neither the specification nor the prior art provide the appropriate guidance to determine that amount of DNA that would satisfy the limitation that the amount of DNA in the phase is "substantial". Is any transfer of plasmid DNA to the organic phase "substantial"?

  
GERRY LEFFERS  
PRIMARY EXAMINER